UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,766	12/12/2003	David Chien	PP-20001.002	9349

27476 7590 04/08/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
POHNERT, STEVEN C	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,766	CHIEN ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,14-18 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,14-18 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/008 has been entered.

Claim Status

This action is in response to the papers filed on 1/22/2008.

Applicant's representative had an interview with the examiner on March 18, to further explain the invention. As a result of the discussion applicant's representative said he would amend the claims that week and would fax the examiner a copy to insure the examiner would be preparing an action to the most relevant claims. The examiner has attempted to contact the representative four times about the status of said amendment, but has not received a response. The following action is thus presented.

Claims 10-13 have been canceled in this amendment.

Claims 1-5, 14-18, 20-34 are pending.

Claims 20-31 are withdrawn from consideration as drawn to a non-elected invention.

Claims 1-5, 14-18 and 32-34 are under examination.

The 102 rejection of Muir has been withdrawn as Muir et al does not teach six outlets the claims now require, each outlet comprising a first section, second section and third section.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 14, 17-18 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husain (US Patent 4,708,850 issue Nov 24, 1987) in view of Muir et al, (WO 1999/26724, published June 3, 1999).

This is a new ground of rejection necessitated by amendment.

It is noted that claim 18 requires either the catalytic molecule and reporter sequence is lyophilized, not both.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, the structure meets the claim limitations.

With regards to claim 1, Husain et al teaches a blood storage and testing device with outlets protruding from the side (see figure 3 and abstract). Husain teaches a container (10) for receiving and storing blood. Husain teaches there are at least 3 outlets protruding from the side (see column 5, line 39). Husain teaches each protruding outlet may be suitably closed (see column 5, lines 52-53). Husain teaches the samples in container 10 are separated from the reagents in outlets protruding form the container (10) by fracturable seals (see figure 6 and 7).

Husain et al does not teach a device with six outlets which comprise three sections, including a lysis buffer and two reagents, wherein in one of the two reagents is either lyophilized or bound to a solid support (claim 1 and 18). Husain does not teach a catalytic molecule and report sequence (claim 18). Husain et al does not teach the device comprises blood platelets.

However, Muir teaches a device and method for detecting target molecules in a biological sample (see abstract). Muir teaches "a test device comprises a receptacle this is attached to at least one sample collection unit housing biological fluid"(see page 3, lines 17-22). Muir teaches, "one compartment comprises at least one cell lysing reagent, another compartment comprises at least one reagent for the inactivation of amplification inhibitors, another compartment comprises at least one reagent for nucleic acid amplification and another compartment comprises at least one reagent for labeling at least one target molecule, wherein the labeled target molecule is subject to a method of detection" (see page 4, lines 21-29). Muir teaches one reagent is affixed to the biocompatible material of the compartment (see page 11, lines 4-7). Muir thus teaches one reagent is bound to a solid support. Muir further teaches, "one target polynucleotide on a solid support"(see page 18, lines 5-6). Muir teaches the use of lyophilized components (see page 56, line 26). Muir teaches the sealing of compartments by thermal or ultrasonic welding (see page 57, lines 24-26). Muir teaches his device advantageously allows the sample and potentially biohazardous materially to be sealed within the device (see page 58, lines 10-13). Muir further teaches his device allows for extended storage and increased shelf life (see page 61, line 10-13).

Muir teaches the receptacle can be completely sequestered from the reaction chamber (see page 10, lines 9-11). Muir teaches this sequestering can be via a valve (see page 12, lines 28-30).

Muir teaches the invention contains breakable partitions that allow mixing of contents from 2 adjacent compartments (see page 3, lines 26-29; page 12, lines 4-11).

Muir teaches the use of PCR amplification to detect a polynucleotide sequence (see page 16, lines 22-23). The polymerase used in PCR is a catalytic enzyme and the primers used for PCR are interpreted as a reporter sequence.

With regards to claim 33 and 34, Muir teaches bodily fluids include blood (see page 3 line 8), which comprise platelets. Muir further teaches assays to determine bacterial growth in platelets (page 75, lines 25-26) using probes to 16S rRNA (see page 76 lines 7-8).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention to combine the teachings of Husain's blood collection with outlets protruding from the side and detection device with Muir's multicompartment blood testing device with lysis buffer in one section, and at least 2 test reagents of which one is either lyophilized or bound to a solid support in another section. The skilled artisan would be motivated to combine the teachings of Husain and Muir because Muir teaches compartmentation of the reagents allows for longer shelf live and storage. Further one of skill in the art would be motivated to make a device with 6 outlets as Husain teaches a device with at least 3 outlets for detecting multiple biological targets in a sample and Muir teaches the detection of multiple nucleic acids in a sample. The artisan would have reasonable expectation of success of combining the structure of Husain and the reagents of Muir as they are both drawn to containers for storage and analysis of biological samples.

4. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husain (US Patent 4,708,850 issue Nov 24, 1987) in view of Muir et al, (WO99/26724, published June 3, 1999) as applied to claim1-5, 14, 17-18 and 32-34 above, and further in view of Shih et al (US Patent 5589332 December 1996).

This rejection is new grounds of rejection necessitated by amendment.

The teachings of Husain and Muir are set forth above in paragraph 3.

Hussain and Muir do not teach a ribozyme or RNA reporter (claim 18) or immobilization of a ribozyme or RNA reporter on a solid support (claim 17).

However, Shih teaches an activated ribozyme complex which includes the ribozyme, co-target molecule (RNA) and disease target molecule (see column 5, lines 1-3) for the diagnostic detection of clinical samples (see column 5 line 65) pathogenic agents, which include viruses, bacteria, or fungi (see column 8 lines 53-54). Shih further teaches use of ribozymes in diagnostics provides high specificity and simple, sensitive and quantitative assays (see column 4 lines 44-46). As Shih teaches, "The methodology for the construction of a regulatable ribozyme, in which a ribozyme sequence is linked to a ligand-binding sequence, placing the activity of the ribozyme under the control of that ligand and requiring its presence for activation or inactivation, is described below" (see column 8, lines 64- top of column 9). Shih further teaches the co-target is a RNA molecule that can be anchored to a solid support (see column 5 lines 11-14) to allow quantification (see column 3, lines33-34).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the diagnostic ribozymes and RNA co-targets of Shih in the blood storage and testing device of Husain and Muir because both Muir and Shih teach testing of blood for pathogens. Shih further teaches ribozymes provide a highly specific simple quantifiable method for detecting virus, fungi, or bacteria in clinical samples. One of ordinary skill in the art would be motivated to improve the blood-testing device of Muir with the diagnostic ribozymes and co-targeting RNA of Shih because the diagnostic ribozymes and co-targets allow a simple sensitive and quantifiable assay of pathogens in clinical samples. The ordinary artisan at the time the invention was made would be further motivated to combine the blood testing device of Muir with the covalently attached co-target of Shih, because it would improve quantitation of clinical sample pathogen assays. The ordinary artisan would be motivated to covalently attach the co-target, because Shih teaches it would allow quanititation. The skilled artisan would have a reasonable expectation of success as Muir and Shih are both drawn to methods of detecting nucleic acids by hybridization.

Response to Arguments

The response asserts that the skilled artisan not have been motivated to modify the device of Muir (now Muir and Shih) with the method of Shih because Shih does not teach or suggest the combination. KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support obviousness. The combination of Husain and Muir teach detection of nucleic acids including pathogens in a blood storage and analysis device and Shih teaches his method “provide a highly specific

simple quantifiable method for detecting virus, fungi, or bacteria in clinical samples" (as previously presented). It would have been prima facie obvious to combine the methods or at least substitute the reagents for detection of Muir and Husain with the reagents taught by Shih.

Further arguments to the Shih's teaching of inactive ribozymes have been addressed in the body of the rejection. However for clarity, Shih teaches, "The methodology for the construction of a regulatable ribozyme, in which a ribozyme sequence is linked to a ligand-binding sequence, placing the activity of the ribozyme under the control of that ligand and requiring its presence for activation or inactivation, is described below" (see column 8, lines 64- top of column 9). Thus Shih teaches in active ribozymes.

The rejection is thus renders the instant claims obvious.

Summary

No claims are allowed over prior art cited.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1634